

## CLAIMS

- 1) Multiparticulate formulation in form of microgranules or micro-tablets having dimensions ranging from 200 to 2000 micrometers, containing Lithium salts, characterized by the fact that said microgranules or micro-tablets have a modified release or that said microgranules or micro-tablets have partly a modified release and partly a conventional release, said formulation having a Lithium salt content of at least 500 mg / g and an in vitro dissolution profile that make it suitable for once-a-day administration.
- 2) Formulation according to claim 1, realized with a Lithium salt dosage up to 1000 mg / dose expressed as Lithium Carbonate.
- 3) Formulation according to claim 1, wherein said Lithium salt content is at least of 900 mg / g.
- 4) Formulation according to claim 1, having the following in vitro dissolution profile:

HOURS	% OF DISSOLVED LITHIUM CARBONATE
1	5 - 25
4	20 - 45
8	40 - 65
12	50 - 80
16	60 - 90
24	> 90

- 5) Formulation according to claim 1, wherein said Lithium salt is chosen from the group including Lithium Carbonate, acetate, glutamate, thionate and sulphate.
- 6) Formulation according to claim 1, wherein the conventional release granules have no coating with agents modifying the dissolution speed, while the modified release granules have a coating with substances chosen from the group including polymers of acrylic and metacrylic acid, cellulose derivatives, stearic acid, paraffin, shellac, zein, or mixtures of the same in any proportion, charged, if necessary, with therapeutically acceptable plasticizers.

7) Formulation according to claim 6, wherein said polymers of acrylic and metacrylic acid are chosen from the group including Eudragit L<sup>®</sup>, Eudragit RS<sup>®</sup> and Eudragit RL<sup>®</sup>.

8) Formulation according to claim 6, wherein said cellulose derivatives are chosen from the group including ethylcellulose, hydroxypropylmethylcellulose, hydroxypropylmethylcellulosephthalate, celluloseacetatephthalate.

9) Formulation according to claim 6, including conventional release granules and modified release granules, in any proportion.

10) Procedure for the preparation of a formulation as defined in claim 1, including the following stages:

a) granulation of a Lithium salt in powder with a solution of a binder chosen from the group including polyvinylpyrrolidone, polyethylene glycol, saccharose and gelatin;

b) sieving of the granules obtained in stage a) ranging from 200 to 2000 micrometers with the obtainment of a conventional release formulation;

c) coating of all or part of the granules obtained in stage b) with the obtainment of a modified release formulation.

11) Procedure according to claim 10, wherein said Lithium salt in powder has a granulometry lower than 100 micrometers.

12) Procedure according to claim 10, wherein said binder solution is a water solution or an organic solvent solution.

13) Procedure according to claim 12, wherein said organic solvent is ethanol.

14) Procedure according to claim 10, wherein said binder solution has a concentration ranging from 3 to 20%.

15) Procedure according to claim 10, wherein the quantity of the binder utilized in the granulation ranges from 0,5% to 15% compared to the Lithium salt.

16) Procedure according to claim 10, wherein said coating of the granules is realized with substances chosen from the group including polymers of acrylic and metacrylic acid, cellulose derivatives, stearic acid, paraffin, shellac, zein, or mixtures of the same in any proportion, charged, if necessary, with therapeutically acceptable plasticizers.

17) Procedure according to claim 16, wherein said polymers of acrylic and metacrylic acid are chosen from the group including Eudragit L<sup>®</sup>, Eudragit RS<sup>®</sup> and Eudragit RL<sup>®</sup>.

5 18) Procedure according to claim 16, wherein said cellulose derivatives are chosen from the group including ethylcellulose, hydroxypropylmethylcellulose, hydroxypropylmethylcellulosephthalate, celluloseacetatephthalate.

1067624-020402  
201020-12929001